

1. BOSC 2017 Nominations

Self Nomination:

Yes

Nominator Information

First Name

Last Name

Nominator Title

Street Address

City

State

Postal Code

Email Address

Phone Number

Mobile Phone

Nominee Information

First Name

Dale

Last Name

Johnson

Nominee Title

Adjunct Professor and President & CEO

Street Address

Exemption 6

Employment Information

Place of Employment/Work:

University of California, Berkeley; Emiliem Inc

Work Street Address

233 Morgan Hall; 6027 Christie Ave

Work City

Berkeley; Emeryville

Work State:

California; California

Work Postal Code

94720-3104; 94608

Work Phone Number

510-316-1197

Work Email Address

daleejohnson@sbcglobal.net

Sector

Other - Write In (Required): Industry and Academia

Qualifications**Primary Area(s) of Expertise**

Computational Toxicology
Animal toxicology studies and biomarkers of toxicity
Systems Pharmacology and Toxicology
Portfolio decision making and research prioritization
Genetic variations and risk susceptibilities

Committee Preference(s)

Chemical Safety for Sustainability and Human Health Risk Assessment Subcommittee

Statement of Interest

As a current member of the CSS and HRA subcommittee, I continue to have a major interest in understanding all the current and planned research activities within this group and adding my knowledge and expertise to provide insight from both an industry and toxicological science standpoint.

Skills/qualifications related to committee preference(s) specified

Experience and expertise in chemical toxicity and human health aspects as a scientist from both industry and academia. I am the author/co-author of 190 journal publications, book chapters and published abstracts. I have been the Chairperson of 10 national/international symposia. Since 1990, I have given 83 invited presentations. I have written over 100 regulatory submissions including expert reports and White papers. I have been the study director of over 200 GLP toxicology studies in multiple species. I am the co-editor of a book "Computational Systems Pharmacology and Toxicology" published in 2017. I was an early innovator in computational toxicology, toxicokinetics/toxicodynamics, gene-chip technologies. I have led and managed large groups of scientists including at the international level.

Other Relevant Information

I have been active in environmental work through the state of California, and at UC Berkeley and the University of Michigan. I was a member of the initial Green Ribbon Science Panel in California and am involved in the Center for Green Chemistry at UC Berkeley. I am a mentor to multiple students and as of 2017, over 100 of my students in my Computational Toxicology course at UC Berkeley have been co-authors of presentations at national scientific meetings

CV/Resume URL

I will upload

2. CV/Resume

Please upload your CV/ Resume.

[DEJ_CV_2017.pdf](#)

3.

BOSC Nomination

Jun 24, 2017 12:50:05 Success: Email Sent to: tracy.tom@epa.gov

4. Thank You for your Submission!

Dale E. Johnson, Pharm.D, Ph.D., DABT

Exemption 6

Dale Johnson has over 30 years of experience as a research and development scientist, manager, executive, and entrepreneur in the biopharmaceutical field working in large pharmaceutical and biotech companies and several start-ups. He also has a long academic career as a lecturer and Adjunct Faculty member in several universities. He is currently an Adjunct Professor at UC Berkeley in Nutritional Sciences and Toxicology and an Adjunct Professor at University of Michigan in Environmental Health Sciences. He received his Ph.D. degree in Toxicology from the University of Michigan where he was an AFPE Fellow. Prior to his Ph.D. work, he received B.S. and Pharm.D. degrees from the University of Michigan College of Pharmacy and completed a residency at UM Medical Center receiving the Squibb National Resident of the Year Award for his work on adverse drug reactions. Currently he is President and CEO of Emiliem, Inc. a privately held biopharmaceutical company. He was also President and CEO of Elara Bioscience LLC a joint venture software company. Prior to Emiliem, he served as VP Drug Assessment & Development (R&D) and VP Preclinical Development at Chiron Corporation, VP Preclinical & Predictive Development at Eos Biotechnology, Sr. Director Toxicology Research & Preclinical Safety at the Medical Research Division of American Cyanamid (Lederle Laboratories), Scientific Director of the Experimental Toxicology Division at International Research and Development Corp., and Sr. Research Toxicologist at Hoechst-Roussel Pharmaceuticals Inc. He was Founder, Chief Scientific Officer & President of ddplatform LLC, a consulting firm in computational toxicology and a technology incubator. Dr. Johnson has been directly involved in the advancement of over 100 compounds from discovery into clinical development of which sixteen have become marketed health care medicinal products and vaccines in the US, Canada, Europe, and Japan. He has personally led multinational projects involving small molecules, recombinant proteins, monoclonal antibodies, gene therapy, photodynamic therapeutics, vaccines, and vaccine adjuvants. In addition, he has been actively involved in portfolio evaluation and decision making in his own and collaborating companies as well as a consultant and advisory board member for outside groups. He has been active in industry-government working groups to improve the drug development processes internationally, consulted on asset evaluation for venture capital firms, and served as an expert for litigation work. He has also been active in environmental work and was a member of the initial Green Ribbon Science Panel for California EPA Department of Toxic Substances Control. Currently he is a member of the US EPA Board of Scientific Counselors Chemical Safety for Sustainability Subcommittee. He is a Diplomate of the American Board of Toxicology, co-inventor on several issued and pending patents, and holds editorial and editorial advisory board positions with several scientific journals.

Education, Awards, and Certifications

B.S., Pharmacy

University of Michigan, 1968

Rho Chi Scholarship Award

Doctor of Pharmacy (Pharm.D.)

University of Michigan, 1968

Roche National Research Award; Collaborator

Pharmacy Residency

University of Michigan Medical Center, 1968-1969

Squibb National Resident-of-the-Year Award

Ph.D., Toxicology

University of Michigan, Interdepartmental, 1976

American Foundation for Pharmaceutical Education Graduate Fellow, 1973-6

Sydnor Barksdale Penick Memorial Fellow, 1974-6

Executive Management Program

University of Michigan Business School, 1993

Board Certified Toxicologist

Diplomate, American Board of Toxicology, 1981 – present

Plenary Lecture Award American College of Toxicology, 2000

Professional Experience

Emiliem, Inc.

President and Chief Executive Officer

Berkeley, CA 2005 - present

Emiliem, Inc. is a privately held biotechnology company focused on the discovery and development of molecular targeted therapeutics and/or assays for rare diseases and unmet medical needs. The Company has international collaborations specifically in the area of turning 'omics information into a pipeline of drug targets and potential clinical candidates

Elara Bioscience LLC

Chief Executive Officer

Berkeley, CA 2012 – 2016

Elara Bioscience LLC was a Joint Venture between Emiliem, Inc. and Pandesa Corp dba Sharevault, Los Gatos, CA. Elara created an enterprise application for chemical information within a secure information sharing portal utilizing secure cloud computing. The platform provided open access as well as a premium subscription model for clients to incorporate confidential business information.

ddplatform LLC

President, Chief Scientific Officer

Emeryville, CA 2000 – 2001, 2005-2009

ddplatform LLC was a privately held biotechnology incubator and technology generator. Early on, scientists created ToxScope™ a chem / tox informatics software system to relate chemical structure to toxicity with LeadScope Inc. a privately held chemoinformatics company and designed a technology platform for Saronyx, Inc., a company specializing in Preclinical Decision Support Systems. As an incubator, the company successfully incubated Emiliem, Inc.

Chiron Corporation

(Acquired by Novartis)

Vice President, Drug Assessment & Development; Vice President, Preclinical Development

Emeryville, CA 1993 -2000; 2003 - 2005

Dr. Johnson was responsible for preclinical research and development including pharmacology, toxicology, pharmacokinetics, drug metabolism, experimental pathology, comparative medicine and translational medicine. He established the Translational Science concept for the corporation. He was the corporate and European expert for biologics and vaccine safety evaluation. His other responsibilities included management of 100 scientific and technical staff, member of both Corporate Research and Development Management Teams, which managed and set strategy for the entire pipeline in research and development, and a member of Joint Management Teams with partners. His groups developed innovative preclinical programs to accelerate clinical trials; Chiron gene therapy designs were adopted by FDA. In addition, he was a member and leader of several discovery, preclinical and clinical project teams, was the non-clinical expert for successful EU registrations, and was a participant in successful FDA ODAC meetings.

Eos Biotechnology

(Acquired by Protein Design Labs)

Vice President, Preclinical and Predictive Development

South San Francisco, CA 2001 – 2003

Eos was a privately held genomics-based discovery and development company with R&D programs for antibodies and antibody fragments for oncology and ocular indications. Dr Johnson was an officer of the Company responsible for preclinical development, project management, assay development and cGMP manufacturing. He was instrumental in transitioning the research company into a R&D company – filing an oncology IND. He increased company value by inventing new ophthalmology indications with Fab fragment of anti-integrin monoclonal antibody. The Company achieved a successful exit via acquisition by Protein Design Labs, Inc.

Medical Research Division, American Cyanamid Company (Lederle Pharmaceuticals)

(Now part of Pfizer through the Wyeth acquisition)

Senior Director, Toxicology Research and Preclinical Safety

Pearl River, NY 1989 –1993

Dr Johnson was responsible for toxicology, pathology, investigative toxicology, and world-wide preclinical submissions. He established the investigative toxicology department. He had direct management of US and Italian laboratories, which included 100+ staff with a multi-national budget. He served as Chair, Corporate Compliance Committee and was a member of the international in-licensing evaluation group. His group was an early industry innovator of toxicokinetic evaluations and photodynamic safety assessment. .

International Research & Development Corp.

(Now MPI Research)

Scientific Director and Head of Experimental Toxicology Division

Mattawan, MI 1980 – 1989

The company was an independent, non-clinical contract research organization conducting outsourced development programs for small molecules, recombinant proteins, antibodies, vaccines, and medical devices for a wide range of disease indications. Dr. Johnson was responsible for the acquisition and conduct of toxicology, pharmacokinetic and metabolism studies; was Study Director on major world-wide safety programs; and served as a consultant to emerging biopharmaceutical companies. He had management responsibility of 200+ staff. Dr. Johnson designed and introduced new carcinogenicity analysis programs, created a metabolism laboratory, and started the first toxicology assessments for biotechnology products.

Hoechst-Roussel Pharmaceuticals Inc.

(Now Sanofi Aventis)

Senior Group Leader, Senior Scientist

Bridgewater, NJ 1976 – 1980

The U.S. pharmaceutical arm of American Hoechst, subsidiary of Hoechst AG.

Dr. Johnson was responsible for the toxicology and teratology laboratories, supervising small groups of research scientists. He was Study Director for safety evaluation studies for US and European projects, was an early innovator of behavioral teratology testing, established the first automated toxicology archive system, and created the first computerized data acquisition system which became the prototype of current commercial systems.

American Society of Hospital Pharmacists

(Now American Society of Health-System Pharmacists)

Assistant Editor, American Hospital Formulary Service

Bethesda, MD 1969-1971

University of Michigan Medical Center

Hospital Pharmacy Resident

Ann Arbor MI 1968 - 1969

Academic Affiliations**University of Michigan**

Adjunct Professor, Department of Environmental Health Sciences, School of Public Health, 2012 – present

Dr. Johnson co-taught a course in Computational Toxicology for graduate students and was affiliated with the Risk Science Center.

Guest lecturer, School of Public Health, 1977-1986. He was a research advisor to several graduate students and guest lecturer in several graduate school courses in the Environmental Health Sciences Department

Lecturer and Instructor, School of Public Health, 1976; 4 credit course “Methods of Toxicology”

University of California, Berkeley

Adjunct Professor, Molecular Toxicology; Department of Nutritional Sciences and Toxicology, 2005- present;

Guest Lecturer, 2000-present. Dr. Johnson was one of the original Founders of the Molecular Toxicology undergraduate major at UC Berkeley while working in the biotechnology industry

He currently is the sole instructor for a 3 credit Computational Toxicology course (NST 121) in the Molecular Toxicology major and the 2 credit Principles of Drug Action course (NST 115) in drug discovery and development.

In addition he mentors undergraduate students in independent study and honors research. He is an affiliated faculty member in the Berkeley Center for Green Chemistry; Health and Environment and is a member of the Editorial Advisory Committee, McNair Scholars.

NST 121, “Computational Toxicology”, has been a requirement for Toxicology majors, minors, and Specialization “majors” since the course inception by Dr. Johnson in 2006. The course is an inquiry-based science course where students work in small cooperative groups and are given tools, data, and basic concepts to solve toxicity-related environmental, public health, and/or disease-oriented problems in novel ways. Outstanding student projects are selected each year to potentially be presented at national scientific meetings. Committed students continue to work on the projects with Dr. Johnson until the meeting deadline for submission, usually during the following Fall semester, which for many students is post-graduation. In March 2017, a major milestone was reached; over 100 different students from this course have been co-authors of these presentations. Another, potential benefit from the course is an opportunity to be selected for an internship at USFDA working in a computational toxicology group. This collaborative program also started in 2006, initially in the Drug Division, and is now in the Food Division. Since its inception, over 20 students from the course, as UC Berkeley graduates, have worked as interns at USFDA, some staying for 2 years.

Mentor:

Honors Research Students, College Nat Resources; Amie Rodgers, William Liu, Elena Chan, Inna Shapiro

Independent study students: John Morrow, Gabriel Quintoriano, Stephanie Chiao, Leana Nguyen, Jennifer Tran, Gianni Xin, Marisela Tan, Emerson Song, Andrew Tanisukarom, Kit Wun Kathy Cheung, Nairi Hartoni, Rachel Chang, Hiroko Irimagawa, Varun Bahl

McNair Scholars Program; Rosa Chan

Committees:

PHD Oral Qualifying Exam; Leona Scanlan, Marianna Brown-Augustine

Co-Chair, MS Thesis committee: Jason Randolph;

Joint program - UCB Health and Medical Sciences, UCSF Medical School

St. John's University

External Graduate School Faculty Member,

Research PI and Ph.D. Dissertation Committee Member, 1990-1993; Mary Ellen Cosenza

Western Michigan University

Adjunct Professor, Department of Biology and Biomedical Sciences; 1987 -1990

Dr. Johnson was the sole instructor of a 4 credit course "Mechanisms in Toxicology"

Kalamazoo College

Undergraduate Research Advisor, 1988-1989

Dr. Johnson was an industrial research mentor for undergraduate biomedical science majors.

Eastern Michigan University

Guest Lecturer, Chemistry Department, 1978-1979

Messiah College

IRI Visiting Industrial Scientist, 1979

Issued Patents

United States

7,276,589

Ramakrishnan V, Powers D, **Johnson DE**, Jeffry U, Bhaskar V. *Chimeric and humanized antibodies to $\alpha 5\beta 1$ integrin that modulate angiogenesis*. Oct. 2, 2007

Amino acid sequences of the heavy and light chain variable regions of the antibody. Pharmaceutical composition and a physiological acceptable carrier

7,285,268

Ramakrishnan V, Powers D, **Johnson DE**, Jeffry U. *Chimeric and humanized antibodies to $\alpha 5\beta 1$ integrin that modulate angiogenesis*. Oct. 23, 2007

Method of treatment of an angiogenesis-associated ocular disease

7,776,585

Ramakrishnan V, Powers D, **Johnson DE**, Jeffry U, Bhaskar V. *Chimeric and humanized antibodies to $\alpha 5\beta 1$ integrin that modulate angiogenesis*. Aug. 17, 2010

Expression vectors comprising specific nucleic acid sequences and the isolated vector-transformed cells

7,879,987

Ramakrishnan V, Powers D, **Johnson DE**, Jeffry U, Bhaskar V. *Chimeric and humanized antibodies to $\alpha 5\beta 1$ integrin that modulate angiogenesis*. Feb. 1, 2011

Isolated nucleic acids encoding polypeptides comprising specific heavy chain amino acid sequences

7,897,148

Ramakrishnan V, Powers D, **Johnson DE**, Jeffry U, Bhaskar V. *Chimeric and humanized antibodies to $\alpha 5\beta 1$ integrin that modulate angiogenesis*. March 1, 2011

Methods of determining pharmaceutical compositions and therapeutically acceptable doses of the antibodies

8,017,116

Ramakrishnan V, Powers D, **Johnson DE**, Jeffry U. *Chimeric and humanized antibodies to $\alpha 5\beta 1$ integrin that modulate angiogenesis*. Sep. 13, 2011

Methods for purification of these antibodies, and methods for their use in treating conditions comprising undesirable tissue angiogenesis

8,309,084

Ramakrishnan V, Powers D, **Johnson DE**, Jeffry U, Bhaskar V. *Chimeric and humanized antibodies to $\alpha 5\beta 1$ integrin that modulate angiogenesis*. Nov. 13, 2012

Defining the source of the constant region is IgG2 or IgG4. Ocular diseases include macular degeneration, Diabetic retinopathy, or choroidal neovascularization. Defines both intravitreal and intravenous injections.

Published Patent Applications (not issued)

PCT/US2006/016067

WO 2006116622 A3

Ching EP, **Johnson DE**, Sudarsanam S.

Novel methods and devices for evaluating poisons. May 14, 2009

Methods and devices useful for evaluating poisons or other chemical entities, and for using such methods to forecast unfavorable drug effects.

PCT/US2007/080113

WO 2008042867 A3

Grant F, **Johnson DE**, Sarma JARP, Subrahmanyam D, Sudarsanam S.

Modulators of multiple kinases. July 17, 2008

Compound structures are provided which should modulate various selected kinases thereby regulating the corresponding kinase signal pathways. These pathways have been shown to regulate biological functions. The compounds, and similar variants, will be useful in therapeutic or diagnostic methods related to said kinases. In particular, improved effects on functional pathways mediated by kinases can be achieved by modulating selected combinations of kinases.

US 12/234,477

US 20090041785 A1

Johnson DE, Jeffry U.

Use of anti-integrin antibodies for reducing scar tissue formation. Feb. 12, 2009

The present invention provides methods that enable the user to identify inhibitors of tissue granulation in and around a wound site, thereby limiting excessive scar formation as the wounded tissue heals. The some granulation inhibitors identified using the methods of the invention inhibit granulation in and around a wound site up to five fold, with a corresponding decrease in the formation of scar tissue when tested on retinal injuries. Granulation inhibitors that can be identified using the methods of the present invention include antibodies, peptides, nucleic acids (aptamers), and non-peptide small molecules.

Professional Affiliations

Scientific Organizations (current)

Society of Toxicology

Former President, Northern California Chapter

American Association Advancement Science

American Chemical Society

Current Member, Expert Panel

Member of US EPA Board of Scientific Counselors, Chemical Safety for Sustainability Subcommittee

Member, Expert Panel (past)

Green Ribbon Science Panel, California Department of Toxic Substances Control
Toxics Information Clearinghouse, California Office of Environmental Health Hazard Assessment
California Breast Cancer and Chemicals Policy Project

Research / Grant Reviewer

Special Emphasis Panel Member, NIH peer review, National Institute of Allergy and Infectious Diseases
Grant Reviewer, NCI Rapid Access to Intervention Development (RAID) program
Grant Referee, Biotechnology and Biological Sciences Research Council, UK

Member, Board of Directors

Emiliem, Inc. (Private), Chairman
Elara Bioscience LLC (past)
Saronyx, Inc. (Private) (past)

Member, Scientific Advisory Board

Institute for Scientific Exchange, Inc.
Kinemed, Inc.(past)
Leadscope, Inc. (past)
Saronyx, Inc., Chairman (past)

Government / Industry Affiliations (past)

BioSafe member; Industry Expert Biologics Advisory group to FDA
Pharmacogenetics Working Group, International advisory group on genetics research in clinical trials
International Conference on Harmonization, Industry participant
Co-principal investigator: Computational Toxicology MTA; CDER and CFSAN, US Food and Drug Administration
Member, Committee to Review NCI's Rapid Access to Intervention Development (RAID) program

Book Editor

Editors: Dale E. Johnson and Rudy Richardson

“Computational Systems Pharmacology and Toxicology”

Issues in Toxicology No. 31
Royal Society of Chemistry, Cambridge, UK (2017)

Editor: Dale E Johnson

“Translational Preclinical Technologies: Predictive Toxicology Approaches for Drug Development”

John Wiley & Sons (Projected publishing date 2018)

Journal Editorial positions**Co-Editor**

Dale E. Johnson, Dennis A. Smith, and B. Kevin Park
Current Opinion in Drug Discovery & Development. The Chemistry of Metabolic and Toxicological Processes,
Current Drugs Ltd., UK , Thomson Reuters 1998-2010

Editor-in-Chief

Journal of Drug Metabolism and Toxicology. OMICS Publishing Group. 2012-present

Editor

"Advances in Computational Toxicology". Special Issue of *International Journal of Molecular Sciences*. Section: *Molecular Toxicology* 2011-12

"Computational Toxicology: Predicting Potential Toxicity of Drugs and Therapeutics". Special Issue of *International Journal of Molecular Sciences*. Section: *Molecular Toxicology* 2014-15

"Frontiers in Drug Toxicity Prediction" " Special Issue of *International Journal of Molecular Sciences*. Section: *Molecular Toxicology* 2017

Editor

"Drug-induced Toxicity and Safe Therapeutic Dosage" Special issue of *Journal of Drug Metabolism and Toxicology* 2011-2012

Other Editorial Positions**Editorial Advisory Board**

"Technologies for the Pharmaceutical Industry"; Sr. Editor, Sean Ekins, Ph.D., D.Sc.
John Wiley & Sons, Inc., Hoboken, NJ. 2007-present

Editorial Board

The Berkeley McNair Research Journal 2011 - present

Editorial Advisory Panel (past)

Drug Discovery Today Supplements (Information Biotechnology), Elsevier Science Ltd., UK

Assistant Editor

American Hospital Formulary Service, American Society of Hospital Pharmacists, Bethesda Md. 1969-1971

Reviewer - current

Key Opinions Journals, Thomson Reuters
OMICS Journals. OMICS Publishing Group
Future Science Group Journals
Expert Opinion Journals
Expert Opinion Drug metabolism & Toxicology
Regulatory Pharmacology and Toxicology
Toxicology and Applied Pharmacology
Expert Review Journals
Journal of Pharmacy and Pharmacology
Expert Opinion, Orphan Drugs

Symposia Chairperson

"**Critical Paths and Approaches for Successful Drug Development**" – Phoenix, November, 2006
The Institute for Scientific Exchange

"**International Conference on Early Toxicity Screening**" – San Diego, February 2004
The Institute for Scientific Exchange

"**International Drug Discovery and Development Summit**" – Honolulu, December 2003
The Institute for Scientific exchange

"**Predictive ADME/Tox**", Philadelphia, February 2003
Center for Business Intelligence

“Reducing the Attrition Rate in Drug Discovery”, London, January, 2003
SMi Conferences - London

“Predictive Toxicology”, Philadelphia, June, 2002
Center for Business Intelligence

“Predictive Toxicology”, Philadelphia, June, 2001
Center for Business Intelligence

“Predictive Toxicology”, Boston, June, 2000
Center for Business Intelligence

“Toxicokinetics and Dynamics in the Design of Preclinical Studies” Chicago, 1993
Drug Information Association

“The Emerging Science of Recombinant Protein Toxicology” San Francisco, 1989
American Association for the Advancement of Science, Annual Meeting

Publications

In preparation/ in press

Larry M. Cai, Jennifer Lu, Stephanie S. Ng, Lisa F. Barcellos , **Dale E. Johnson**. Identification of Genetic-Chemical Interactions that Link Cigarette Smoking to Rheumatoid Arthritis. (manuscript in revision)

JeBaily L, Chan E, **Johnson D** Chemicals causing mammary tumors in rats and relevance to human breast cancer. Systems toxicology analyses of modes of action (Manuscript in revision)

Published

Lindsay C. Burrage, Qin Sun, Sarah H. Elsea, Ming-Ming Jiang, Sandesh C.S. Nagamani, Arthur E. Frankel, Evertt Stone, Susan E. Alters, **Dale E. Johnson**, Scott W. Rowlinson, George Georgiou, Brendan H. Lee (2015) Human recombinant arginase enzyme reduces plasma arginase in mouse models of arginase deficiency. *Human Molecular Genetics*, 24(22) 6417-6427

Megan Schwarzman, Janet Ackerman, Shanaz Dairkee, Suzanne Fenton, **Dale Johnson**, Kathleen Navarro, Gwendolyn Osborne, Ruthann Rudel, Gina Solomon, Lauren Zeise, Sarah Janssen (2015) Screening for Chemical Contributions to Breast Cancer Risk: A Case Study for Chemical Safety Evaluation. *Environ Health Perspectives*. 123(12) 1255-1264.

Dale E Johnson (2014) Fast-tracking an orphan drug indication within a broader development project. *Expert Opinion Orphan Drugs* 2 (2) 107-111

Dana Felker, Alexandra Lynn, Sue Wang, **Dale Johnson** (2014) Evidence for a Potential Protective Effect of Carnitine-Pantothenic Acid Co-treatment on Valproic Acid-Induced Hepatotoxicity. *Expert Rev Clin Pharmacol* 7(2) 211-218

Johnson D (2013) 4 (4) Toxicity Prevention, Therapeutic Drug Monitoring, and Spheres of Influence *J Drug Metab Toxicol* 4: e118. doi:10.4172/2157-7609.1000e118

Dale E Johnson (2013) Fusion of nonclinical and clinical data to predict human drug safety. *Exp Rev Clin Pharmacol*. 6(2) 185-195. Doi:10.1586/ecp.13.3

Dale E Johnson (2012) Estimating human cancer risk from rodent carcinogenicity studies: The changing paradigm for pharmaceuticals. *J Drug Metab Toxicol*. 3 (6) Open Access. <http://dx.doi.org/10.4172/2157-7609.1000e114>

Dale E. Johnson (2012) Predicting drug safety: Next generation solutions. *J Drug Metab Toxicol* 3 (2) Open Access <http://dx.doi.org/10.4172/2157-7609.1000e106>

Johnson Dale E, Srinivasan Subha, Bingham Jonathan, and Sudarsanam Sucha. (2012) Translational biology approach to identify causative factors for rare toxicities in humans and animals. *Curr Drug Discov Technol* 9(1) 77-80.

Dale E. Johnson (2010) Biotherapeutic first in human dose selection: making use of preclinical markers *Expert Rev Clin Pharmacol* 3(2) 231-242

Schwarzman M, Janssen S, Rudel R, Zeise L, Guth J, Solomon G, **Johnson D**, Dairkee S, Morello-Frosch R, Fenton S, Melnick R, Latimer J, Coglian V (2010) Pathways to Breast Cancer: A case study for innovation in chemical safety evaluation. A report of the Breast Cancer and Chemicals Research project. *Cal Breast Cancer Research Program*. pp 1-36

Johnson DE, Smith DA, and Park BK (2010) Immunomodulatory Therapies and the risk of Opportunistic Infections *Current Opinion Drug Disc Develop* 13 (1) 20-22

Elena Chan, Marisela Tan, Gianni Xin, Sucha Sudarsanam, and **Dale E. Johnson** (2010) Interactions between Traditional Chinese Medicines and Western Therapeutics *Current Opinion Drug Disc Develop* 13(1) 58-73

Sucha Sudarsanam and **Dale E. Johnson** (2010) Functional consequences of mTOR inhibition *Current Opinion Drug Disc Develop* 13(1) 39-48

Johnson DE, Smith DA, and Park BK (2009) Pharmacogenomics and adverse drug reactions; prospective screening for risk identification. *Current Opinion Drug Disc Develop* 12(1) 27-30

Srinivasan S, Bingham J, and **Johnson DE** (2009) The ABC's of Human Alternative Splicing: A Review of ATP-Binding Cassette Transporter Splicing. *Current Opinion Drug Disc Develop* 12(1) 149-158

Liu W and **Johnson DE** (2009) Clustering and its application in multi-target prediction. *Current Opinion Drug Disc Develop* 12(1) 98-107

Chiao S, Romero D, **Johnson DE** (2009) Current HIV Therapeutics: mechanistic and chemical determinants of toxicity. *Current Opinion Drug Disc Develop* 12(1) 53-60

Johnson DE, Park BK, and Smith DA (2008) Ethnic variation in drug response: Implications for the development and regulation of drugs. *Current Opinion Drug Disc Develop* 11(1) 29-31.

Johnson DE, Smith DA, and Park BK (2007) Biomarkers: The *piece de resistance* of innovative medicines. *Current Opinion Drug Disc Develop* 10(1) 22-24.

Ching EP, Turner SM, Sudarsanam S, and **Johnson DE** (2007) Critical paths and approaches for successful drug development. *Current Opinion Drug Disc Develop* 10 (1) 25-28.

Ramakrishnan V, Bhaskar V, Law DA, Wong MH, DuBridge RB, Breinberg D, O'Hara C, Powers DB, Liu G, Grove J, Hevezi P, Cass KM, Watson S, Evangelista F, Powers RA, Finck B, Wills M, Caras I, Fang Y, McDonald D, **Johnson D**, Murray R, Jeffry U (2006) Preclinical evaluation of an anti-alpha5beta1 integrin antibody as a novel anti-angiogenic agent. *J Exp Ther Oncol* 5(4) 273-86.

Mendelson J, Barker A, Doroshow J, Tomaszewski J, Allison J, Calzone F, Clark D, Cornetta K, Frost P, Gerson S, Grever M, Hait W, Jaffee E, **Johnson D**, Kramer R, Lyerly H, Morin M, Park J, Raubitschek A, Reynolds C, and Weiner L. (2006) Report of the Review of the National Cancer Institute's Rapid Access to Intervention Development (RAID) Program. *NCI RAID Final Report (061106) c*, 1-26.

Smith DA, **Johnson DE** and Park BK (2006). Safety of drugs can never be absolute. *Current Opinion Drug Disc Develop* 9(1): 26-28.

Johnson DE and Rodgers AD (2006). Computational toxicology: Heading toward more relevance in drug discovery and development. *Current Opinion Drug Disc Develop* 9(1): 29-37.

Johnson DE, Smith DA and Park BK (2005). Safety/toxicity threshold concepts in drug discovery and development. *Current Opinion Drug Disc Develop* 8(1): 24-26.

Johnson DE, Smith DA and Park BK (2004). Linking toxicity and chemistry: think globally but act locally? *Current Opinion Drug Disc Develop* 7(1): 33-35.

Smith DA, **Johnson DE**, and Park BK (2003). Use of microdosing to probe pharmacokinetics in humans – Is it too much for too little? *Current Opinion Drug Disc Develop* 6(1): 39-40.

Grushenka H.I. Wolfgang and **Dale E. Johnson** (2002) Web Resources for Drug Toxicity. *Toxicology*: 173, 1-2: 67-74.

Dale E. Johnson, Dennis A. Smith, and B. Kevin Park (2002). The chemistry of metabolic and toxicological processes. *Current Opinion Drug Disc Develop* 5(1): 31-32.

Dale E. Johnson and Grushenka H.I. Wolfgang (2001). Assessing the Potential Toxicity of New Pharmaceuticals. *Current Topics in Medicinal Chemistry*. 1:233-245.

Dale E. Johnson (2001) The future of biotechnology testing in the next decade: A perspective. ACT Plenary Lecture. *International J Toxicology*. 20:1-5.

Dale E. Johnson, Paul E. Blower Jr., Glenn J. Myatt, and Grushenka H.I. Wolfgang (2001) Chem-tox informatics: Data mining using a medicinal chemistry building block approach. *Current Opinion Drug Disc Develop*. 4(1): 92-101

Dale E. Johnson, Dennis A. Smith, and B. Kevin Park (2001). The chemistry of metabolic and toxicological processes. *Current Opinion Drug Disc Develop* 4(1): 27-28.

D. E. Johnson (2001) The optimal fragmentation principle. *Drug Discovery Today*. 6, 175

Roehl HH, Leibbrandt ME, Greengard JS, Kamantigue E, Glass WG, Giedlin M, Boekelheide K, **Johnson DE**, Jolly DJ, Sajjadi NC (2000) Analysis of testes and semen from rabbits treated by intravenous injection with a retroviral vector encoding the human factor VIII gene: No evidence for germline transduction. *Human Gene Therapy*, 11(18) 2529-40.

Dale E. Johnson and Grushenka H.I. Wolfgang (2000) Predicting human safety: screening and computational approaches. *Drug Discovery Today*. 5, 445-454.

Dale E. Johnson, Dennis A. Smith, and B. Kevin Park (2000) The chemistry of metabolic and toxicological processes. *Current Opinion Drug Disc Develop* 3(1): 29.

Johnson D (1999) The discovery-development interface has become the new interfacial phenomenon. *Drug Discovery Today*, 4, 535-536.

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Invited Presentations (since 1990)

School of Public Health, UC Berkeley Berkeley, CA, February 2017
Pharmacogenomics in “Molecular and Genetic Epidemiology”

School of Public Health, UC Berkeley Berkeley, CA, April 2016
Pharmacogenomics in “Molecular and Genetic Epidemiology”

School of Public Health, UC Berkeley Berkeley, CA, March 2015
Pharmacogenomics in “Molecular and Genetic Epidemiology”

School of Public Health, UC Berkeley Berkeley, CA, March 2014
Pharmacogenomics in “Molecular and Genetic Epidemiology”

Health Canada Ottawa, Canada, January 2014
Computational Methods linking Traditional Chinese Medicine (TCM) and Western Therapeutics

29th Annual Statewide Environmental Conference San Diego, November 2013
The Lists and Clearinghouse from the Safer Consumer Products Regulation and Protection of Confidential Business Information

Society of Toxicology Symposium “The Promise of Translational and Integrative Assessments of Dietary Supplements, Traditional Medicines, and Herbal Drugs”, San Antonio, Texas, March, 2013
Computational Methods Linking Traditional Chinese Medicine (TCM) and Western Therapeutics

School of Public Health, UC Berkeley Berkeley, CA, Feb 2013
Pharmacogenomics in “Molecular and Genetic Epidemiology”

Society of Toxicology Continuing Education Course San Francisco, March 2012
Frontiers and Applications in Predictive Toxicology: In Silico Methods for Risk Assessment, Toxicology, and Metabolism

Molecular Medicine Tri-Conference 2012 Pre-Conference Short Course (SC12) San Francisco, Feb 2012
First-in-Human Study and Risk Mitigation Strategy for Biologics

School of Public Health, UC Berkeley Berkeley, CA, Feb 2012
Pharmacogenomics in “Molecular and Genetic Epidemiology”

Annual Statewide Environmental Summit San Diego, November, 2011
Green Chemistry Expert Panel

Molecular Medicine Tri-Conference 2011 San Francisco, Feb 2011
Fast-tracking an orphan drug indication within an oncology development project

Molecular Medicine Tri-Conference 2011 Pre-Conference Short Course (SC5) San Francisco, Feb 2011
Early Drug Development and First-in-Human Dose Regimen: Biologics

School of Public Health, UC Berkeley – Berkeley, CA. Feb 2011
Pharmacogenomics in “Molecular and Genetic Epidemiology”

EPPIC Life Science Conference – Palo Alto, CA January 2011
Partnering Paradigm for Life sciences: Clinical Trials: Molecules to Medicines

Green Chemistry in Higher Education. California DTSC and BCGC – Berkeley, CA October 2010
UC Berkeley Undergraduate Research Education Curriculum (Computational Toxicology)

From Research to Action: Tools for Change – Oakland, CA. September 2010
Making chemical testing relevant to breast cancer: The California Breast Cancer and Chemical Policy Project

Human Health Hazard Indicators Workshop, California EPA – Sacramento, CA. March 2010
Computational toxicology screening methods

School of Public Health, UC Berkeley – Berkeley, CA. March 2010
Pharmacogenomics in “Molecular and Genetic Epidemiology”

Novel Therapeutics Biologics: Innovative Molecules and Mechanisms – MPI Research Summit – Augusta, MI, Oct, 2009
Targeting the extracellular matrix with function-blocking Mabs can control angiogenesis and tissue granulation

School of Public Health, UC Berkeley – Berkeley, CA. March 2009
Pharmacogenomics in “Molecular and Genetic Epidemiology”

Cambridge Healthtech Institute 16th International Molecular Medicine Tri-Conference. Shaping Future Medicine – San Francisco, CA, February 2009
Preclinical Markers Relevant for First in Human Dose Selection with an Anti-Integrin Monoclonal Antibody

MichBio. Biosciences Policy Summit – Novi, MI, Nov 2008
Expert Panel Participant

College of Pharmacy, Pharmaceutical Sciences, U of Michigan – Ann Arbor, MI, Sept, 2008
Novel Approaches for Anti-angiogenic Therapeutics

Dept. of Chemistry, U C Berkeley – Berkeley, CA Sept, 2008
Green Chemistry from a Toxicology Viewpoint

Dept. of Nutritional Sciences and Toxicology, U C Berkeley – Berkeley, CA, April, 2008
Multi-functional Molecular Targeted Cancer Therapeutics

ISE's International Drug Discovery and Development Summit – Phoenix, November, 2006
Impact of Critical Path Initiative on Drug Discovery and Development

Xoma Corporation – Berkeley, CA, September 2006
Translational medicine

Keystone Symposium – Meeting the Challenges of Drug Discovery – Vancouver, BC, January 2005
Computational approaches for the prediction of drug-induced toxicity

ISE's International Drug Discovery and Development Summit – San Diego, December 2004
Innovative Strategies for Successful Drug Development

ISE's International Conference on Early Toxicity Screening – San Diego, February 2004
Predictive toxicity screening – Future directions for in silico applications

ISE's International Drug Discovery and Development Summit – Honolulu, December 2003
Linking with Emerging Technologies

IBC's Drug Discovery Technology 2003 – Boston, August 2003
Toxicity Screening – the Unmet Need

CBI's “Predictive ADME/Tox”, Philadelphia, February 2003
Toxicophores and Biomarkers – Creating an Integrated Approach for HTS and In Silico Prediction

SMI's “Reducing the Attrition Rate in Drug Discovery”, London, January, 2003
New Approaches for Predictive Toxicology

ISE's “International Drug Discovery and Development Summit: From Lead to Drug in Five Years”, Honolulu, HI, December, 2002
New Approaches for Predictive Toxicology

CBI's “Predictive Toxicology”, Philadelphia, June, 2002
Toxicology information used to design better chemical libraries

DIA's Annual Meeting, Chicago, June 2002
Biomarkers in Preclinical Development

AAPS – FDA: Integration of Exposure Response Relationships in Drug Development and Regulatory Assessment – A Revisit with a Decade of Experience, Crystal City, VA, June, 2002
Strategies in the use of exposure and response relationships in the selection and development of new drug candidates: An Industry perspective

LabAutomation 2002, Palm Springs, CA, January 2002
Database content for in silico toxicology predictions

ISE's "2nd International Conference on early toxicity screening: In silico, in vitro and high throughput screening approaches", Washington, DC, December, 2001
The use of chemoinformatics in in silico toxicology evaluation

CBI's "Predictive Toxicology", Philadelphia, June, 2001
Chem-tox informatics in drug discovery: the use of large sets of toxicology information in the design of virtual chemical libraries

Genetic Toxicology Association's "Determining Chemical Structure – Mutagenicity Relationships Using Computational Toxicology", Newark, DE, May, 2001
Predicting genotoxicity in virtual drug discovery

Society of Toxicology Annual Meeting, San Francisco, March, 2001
Symposium on Computational Toxicology
Chem-tox informatics in pharmaceutical R&D

UCSF Program in Biomedical Informatics, San Francisco, March, 2001
Predicting toxicity by computational methods during drug discovery

InfoTech Pharma 2001, London, February, 2001
Chem-tox informatics: data mining with large sets of chemistry and toxicology information using a medicinal chemistry building block approach

NCAC-SOT and Assoc Govt Tox Symposium: "Computational Approaches for Predicting the Toxicity of Chemicals", Bethesda MD, December, 2000
Drug discovery models

IBC's "Early ADME and Toxicology in Drug Discovery", San Diego, November, 2000
Chem-tox Informatics: data mining using a medicinal chemistry building block approach

American College of Toxicology Annual Meeting, San Diego, November, 2000
Plenary Lecture
The future of biotechnology testing in the next decade: A perspective

IBC's "Trends in Pharmaceutical Preclinical Development", Amsterdam, October, 2000
The in silico discovery-development interface: new approaches for merging cheminformatics with safety prediction

UC Berkeley Science Seminar Series, Berkeley CA, September, 2000
Chem-tox informatics: toxicology data mining using a medicinal chemistry building block approach

American Chem Society Annual Meeting, Washington DC, August, 2000
Computational Toxicology and Virtual Drug Design

CBI's "Predictive Toxicology", Boston, June, 2000
Use of in silico approaches as predictive toxicology tools

American Chem Soc Annual Meeting, San Francisco, March 2000
e-DDI: the virtual discovery-development interface

IBC's 5th Annual Meeting on Pharmaceutical Preclinical Development, London, 1999
Accelerating Preclinical Development of Biotech Products

2nd US Biotechnology Symposium, Washington DC, 1999
Selection of preclinical CROs for biopharmaceutical products

IBC's 8th Annual Conf on High-throughput screening, Berkeley, CA, 1999
Managing the transition from Discovery to Development

IBC's 3rd Annual Conf on Drug Discovery Technologies, Amsterdam, 1999
Managing the increasing focus on the drug discovery/ pre-clinical interface: optimizing drug candidate selection

IBC's Conf on Models of Human Response for ADME and Toxicity, New Orleans, 1999
Pre-clinical simulations of human outcomes: 1999 status

The Biopharmaceutical Conference in Europe, Barcelona, 1998
Preclinical development: will future technologies make a difference?

IBC's Early ADME and Toxicology in Drug Discovery, Berkeley, CA, 1998
The Discovery-Development Interface

IRI's "Accelerating Preclinical Development", San Francisco, 1998
Presentation of the Pharmacology and Toxicology Information in an EC Marketing Application

IBC's 2nd International Exposition and Symposium on Drug Discovery Technology, San Diego, 1997
Use of bDNA Technology for early toxicity assessments

Centre for Medicines Research International, "Safety Evaluation of Biotechnologically-derived Pharmaceuticals: Facilitating a Scientific Approach" Wych Cross, East Sussex, UK, 1997
Interferons and Interleukins

IBC's World Summit on Molecular Toxicology, Lake Buena Vista, FL, 1996
Molecular Screening of Potential Lead Compounds from Combinatorial Chemistry Libraries

Southern California Biotechnology Discussion Group, San Diego, 1995
Safety Evaluation of Biotechnology Products

Corning Hazleton's "The use of Primates in Biotechnology Research" San Francisco, 1995
Toxicokinetic/toxicodynamic considerations in primate toxicology studies

DIA's "Pharmacokinetics and Pharmacodynamics in the Development of Biotechnology Products"
New Orleans, 1995
Use of Toxicokinetics in dose selection of toxicology studies

AAPS and Amer Coll Clin Pharmacol: "Preclinical and Clinical Pharmacology Issues with Proteins and Peptides" San Diego, 1995
Evaluation of tissue dosimetry in in vitro and in vivo test systems for safety assessment

Biowest '95, "Preclinical Issues for Biopharmaceuticals and ICH Harmonization", San Jose, CA, 1995
Effects of changing the therapeutic indications on preclinical issues

DIA's "Pharmacokinetics and Pharmacokinetics in the development of Biotechnology Products: Practical Applications", New Orleans, 1995
Use of Toxicokinetics in dose selection of toxicology studies

Society of Toxicology, Northeast Chapter, "The Impact of Biotechnology on Toxicology" Sturbridge, MA, 1993
Scientific issues in the safety evaluation of biotechnology-related products

DIA's "Toxicokinetics and Dynamics in the Design of Preclinical Studies" Chicago, 1993
Toxicokinetic/toxicodynamic concepts in concentration-oriented preclinical research

St. John's University Science Lecture Series, Jamaica, NY, 1993
Drug Toxicodynamics: Current Concepts

AAPS "Advances in Toxicokinetics" San Antonio, 1992
Implementation of toxicokinetic data in the design of safety assessment studies

5th National Forum on AIDS, Hepatitis, and other Blood-borne Diseases: "Science and Policy – A Time of Transition", Atlanta, 1992
The effect of daily dosing regimen on the multiple-dose toxicity of FLT in laboratory animals

U of Michigan, School of Public Health Lecture Series, Ann Arbor, MI, 1992
Toxicokinetics in Drug Research

NIH National Cooperative Drug Discovery Groups for the treatment of HIV Infection, "Frontiers in HIV Therapy" San Diego, 1991

The toxicology of 3'-deoxy 3'-fluorothymidine (FLT) in laboratory animals

AAPS "Pharmacokinetic/pharmacodynamic Workshop" Pearl River, NY, 1991

Toxicokinetics from a Toxicology Perspective

Lederle Science Lecture Series Montvale, NJ, 1991

Current Concepts in the Development of Safe Drugs

IRDC's "Toxicological, Regulatory and Commercial Aspects of Biotechnology Products" Kalamazoo, MI, 1990

Correlation of Pre-clinical and Clinical Toxicity with Biotechnology Products